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Counsel for Plaintiff Intra-Cellular Therapies, Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

INTRA-CELLULAR THERAPIES, INC.,

Plaintiff,

v.

AUROBINDO PHARMA LTD.
AUROBINDO PHARMA USA, INC.,
ALKEM LABORATORIES LTD., DR.
REDDY'S LABORATORIES INC. DR.
REDDY'S LABORATORIES LTD.,
HETERO USA, INC., HETERO LABS
LTD. UNIT-V, HETERO LABS LTD.,
MSN LABORATORIES PRIVATE LTD.,
SANDOZ INC., ZYDUS
PHARMACEUTICALS (USA) INC., and
ZYDUS LIFESCIENCES LTD.,

Defendants.

**Civil Action No. 3:24-cv-04264
(MAS)(JBD) (Consolidated)**

**INTRA-CELLULAR THERAPIES, INC.’S ANSWER TO THE
COUNTERCLAIMS OF DEFENDANTS ZYDUS
PHARMACEUTICALS (USA) INC. AND ZYDUS LIFESCIENCES LIMITED**

Plaintiff Intra-Cellular Therapies, Inc. (“Plaintiff”), by its attorneys, hereby reasserts as if fully set forth herein each of the paragraphs of Plaintiff’s Complaint (Case No. 3:24-cv-08856,¹ Dkt. No. 1) and answers the counterclaims of Defendants and Counterclaim Plaintiffs Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”) and Zydus Lifesciences Limited (“Zydus Lifesciences”) (collectively, “Zydus”) using the paragraph numbers of Zydus’s counterclaims, D.I. 89, as follows:

THE PARTIES

1. On information and belief, admitted.
2. On information and belief, admitted.
3. Admitted.

JURISDICTION AND VENUE

4. The allegations in paragraph 4 purport to characterize various statutes, which speak for themselves. To the extent a response is required, Plaintiff does not contest subject matter jurisdiction for purposes of this action.

5. The allegations in paragraph 5 contain legal allegations to which no response is required. To the extent a response is required, Plaintiff does not contest personal jurisdiction for purposes of this action.

6. The allegations in paragraph 6 purport to characterize various statutes, which speak for themselves. To the extent a response is required, Plaintiff does not contest venue for purposes of this action.

¹ While Plaintiff filed its claims in an individual suit, Defendants’ counterclaims, and this answer to those counterclaims, were filed in the consolidated action, Case No. 3:24-cv-04264.

REGULATORY FRAMEWORK

7. The allegations in paragraph 7 purport to characterize various statutes and regulations, which speak for themselves.

8. The allegations in paragraph 8 purport to characterize various statutes and regulations, which speak for themselves.

9. Admitted.

10. The allegations in paragraph 10 purport to characterize various documents, which speak for themselves.

11. Admitted.

12. Admitted that Plaintiff submitted on June 11, 2024, the '617 patent to FDA for listing in the Orange Book concerning NDA No. 209500 for CAPLYTA® (lumateperone tosylate) capsules. The remaining allegations in paragraph 12 contain legal allegations to which no response is required.

13. The allegations in paragraph 13 purport to characterize various documents, which speak for themselves.

14. Admitted.

15. Admitted that Plaintiff submitted on August 29, 2024, the '459 patent to FDA for listing in the Orange Book concerning NDA No. 209500 for CAPLYTA® (lumateperone tosylate) capsules. The remaining allegations in paragraph 15 contain legal allegations to which no response is required.

ZYDUS USA'S ANDA

16. On information and belief, admitted that Zydus USA submitted to FDA Abbreviated New Drug Application No. 218652 ("Zydus's ANDA") seeking FDA approval to

engage in the commercial manufacture, use, or sale of lumateperone capsules, 10.5 mg, 21 mg, and 42 mg (“Zydus’s ANDA Product”).

17. On information and belief, admitted.

18. The allegations in paragraph 18 purport to characterize a document, which speaks for itself.

19. Admitted.

COUNT I

(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,980,617)

20. Plaintiff realleges and incorporates by reference each of its responses to the foregoing paragraphs 1–19 above.

21. Admitted that there is an actual case or controversy between Zydus and Plaintiff with respect to Zydus’s liability for infringement of the ’617 patent. Denied that Zydus is entitled to any of the relief it seeks. Any remaining allegations in paragraph 21 are denied.

22. Denied.

COUNT II

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,980,617)

23. Plaintiff realleges and incorporates by reference each of its responses to the foregoing paragraphs 1–22 above.

24. Admitted that there is an actual case or controversy between Zydus and Plaintiff with respect to Zydus’s liability for infringement of the ’617 patent. Denied that Zydus is entitled to any of the relief it seeks. Any remaining allegations in paragraph 24 are denied.

25. Denied.

COUNT III

(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,070,459)

26. Plaintiff realleges and incorporates by reference each of its responses to the foregoing paragraphs 1–25 above.

27. Admitted that there is an actual case or controversy between Zydus and Plaintiff with respect to Zydus's liability for infringement of the '459 patent. Denied that Zydus is entitled to any of the relief it seeks. Any remaining allegations in paragraph 27 are denied.

28. Denied.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,070,459)

29. Plaintiff realleges and incorporates by reference each of its responses to the foregoing paragraphs 1–28 above.

30. Admitted that there is an actual case or controversy between Zydus and Plaintiff with respect to Zydus's liability for infringement of the '459 patent. Denied that Zydus is entitled to any of the relief it seeks. Any remaining allegations in paragraph 30 are denied.

31. Denied.

PRAYER FOR RELIEF

The “WHEREFORE” paragraph and subparagraphs A–G following paragraph 31 state Zydus's Prayer for Relief, to which no response is required. To the extent a response is required, Plaintiff denies that Zydus is entitled to any of the relief in the Prayer for Relief, or to any relief whatsoever.

Any allegation in the Counterclaims not expressly admitted herein is hereby denied.

AFFIRMATIVE DEFENSES TO COUNTERCLAIMS

Plaintiff affirmatively states the following defenses, undertaking the burden of proof only to the extent required by law:

FIRST AFFIRMATIVE DEFENSE

Each of Zydus's Counterclaims fails to state a claim upon which relief can be granted. For example, Zydus has alleged no facts that, if true, would show that the '617 and '459 patents are invalid or unenforceable for any reason.

SECOND AFFIRMATIVE DEFENSE

Zydus's Counterclaims fail to state a claim upon which relief for exceptional cases under 35 U.S.C. § 285 can be granted.

* * *

Plaintiff reserves the right to supplement and/or amend these affirmative defenses as may become available or apparent during discovery proceedings.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

- (a) A judgment that the '617 and '459 patents have been infringed under 35 U.S.C. § 271(e)(2) by Zydus's submission to the FDA of Zydus's ANDA;
- (b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Zydus's ANDA Product, or any other drug product that infringes or the use of which infringes the '617 and '459 patents, be not earlier than the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;
- (c) A preliminary and permanent injunction enjoining Zydus, and all persons acting in concert with Zydus, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product, or any other drug product covered by or whose use is covered by the '617 and '459 patents, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product, or any other drug product covered by or whose use is covered by the '617 and '459 patents, prior to the expiration of said

patents, will infringe, induce the infringement of, and contribute to infringement by others of said patents;

- (e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- (f) Costs and expenses in this action; and
- (g) Such further and other relief as this Court may deem just and proper.

Dated: January 9, 2025

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